(Draft for discussion)

1 2 3	NIOSH Topic Page Chest Radiography
	Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings
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5	NOTICE: NIOSH Seeking Public Comment
6 7 8 9 10 11 12 13	The National Institute for Occupational Safety and Health is using the issuance of the new International Labour Office (ILO) Classification of Radiographs as an opportunity to expand its Website on the B Reader Program and use of the ILO system. NIOSH-certified B readers use the internationally-recognized ILO system to classify chest radiographs for the presence and severity opulmonary parenchymal and pleural changes potentially caused by exposure to dusts such as asbestos, silica, and coal mine dust. The revised program Web site provides more information about radiographic reading and the ILO system including recommendations or "best practices" for use of the ILO system in different settings.
14 15 16 17 18 19	Below is a draft of "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings." We are seeking public comment for this document. Please review it and submit your comments to <a "blind"="" (niosh)="" 1)="" 2)="" 3)="" 4)="" 5)="" addresses="" and="" assess="" at="" avoid="" b="" beginning="" being="" biases="" by="" cases="" certified="" chest="" classification="" classified,="" concern="" control="" critical="" desirability="" details="" each="" employing="" employment="" films="" films.<="" for="" from="" health="" href="https://cww.cwm.cwm.cwm.cwm.cwm.cwm.cwm.cwm.cwm.</td></tr><tr><td>20
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22</td><td>Thank you in advance for your input. It is important to us that we consider many different viewpoints in this document. Also, we are interested in your feedback on the whole Web site. Please feel free to send any comments or suggestions to the same address.</td></tr><tr><td>23
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25</td><td>Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.</td></tr><tr><td>26
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37</td><td>The International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses was developed primarily for use in epidemiological research. In this classification system, parenchymal lung abnormalities on chest radiographs are identified and radiographic severity is classified on a 12-point scale ranging from 0/- to 3/+ by comparing the radiographs to ILO standard films. Pleural abnormalities are also identified and described. Although the ILO system was developed primarily for use in research, the standardized descriptions of chest radiographs used in the system, and even the scoring system itself, have been applied in a wide range of settings. In some non-research settings, how or even whether ILO Classification should be applied has been controversial. In this document, guidance is provided for the roles of ILO Classification and NIOSH-certified B Readers performing ILO Classification in several important settings. Setting-specific suggestions for how ILO classifications should be performed are also provided.</td></tr><tr><td>38
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Recommended Application of the ILO Classification System in **Medical Diagnosis**

3 4 5 Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final 6 text will modified based on input received from stakeholders.

- 7 8 9 The chest radiograph plays a key role in clinical diagnosis of pneumoconiotic and other pulmonary diseases. Radiographic abnormalities can indicate the presence and extent of pulmonary disease.
- Radiographic findings alone are generally insufficient for diagnosis of pulmonary diseases.
- 10 Diagnosis generally requires consideration of additional information such as clinical history,
- physical examination, and other types of medical tests. Still, radiographic differential diagnosis can
- 12 establish a range of diagnostic possibilities and is often a critical part of disease diagnosis. The
- 13 outcome sought from disease diagnosis is to prescribe appropriate treatment that alleviates
- 14 disease morbidity and mortality.

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15 **Summary of Recommendations**

ILO Classification:	No (but principles used in system can be applied)
B Reader certification:	No (but the knowledge is useful in demonstrating competence)
Multiple readings:	Single (unless further opinion necessary)
Blind reading:	Not necessary
Quality control films:	Not necessary

16 Symptomatic dust-exposed workers should see their physician right away

- 17 Workers who suffer dust exposure at work or who have a history of dust exposure and have chest
- 18 symptoms, such as shortness of breath, cough, or any other respiratory health concerns, should
- 19 ask their doctor about these symptoms right away.
- Workers exposed to either coal mine dust or other kinds of dusts, such as asbestos or silica dust,
- and have no regular doctor can find a doctor skilled in occupational diseases by looking at the
- Association of Occupational and Environmental Clinics (AOEC) Web site (external link). The AOEC
- 20 21 22 23 24 25 provides a list of occupational and environmental clinics and resources by state. Other types of
- doctors, such as those specializing in Pulmonary Diseases, are also able to provide expert
- diagnosis and treatment.
- Coal miners who do not have a regular doctor can find a doctor who knows about mining-related
- health problems at one of the U.S. Government-supported Black Lung Clinics. These clinics
- typically offer benefits such as counseling, testing, and treatment. They provide services such as
- chest radiographs, pulmonary function testing, other laboratory tests, and education about
- 26 27 28 29 30 respiratory diseases for miners and their families. Active, inactive, and retired coal miners who
- suffer from chronic respiratory disease are eligible for these services. Services vary from clinic to
- clinic, so check with the nearest Black Lung Clinic (external link) for specifics.

Further information

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34 The role of radiography in diagnosis

- Among those with a history of workplace dust exposure, chest radiographs are part of medical
- 36 37 testing for lung diseases like coal workers' pneumoconiosis, silicosis, and asbestosis (that is, the
- pneumoconioses). The goal of medical diagnosis is for the physician to accurately and quickly
- identify patients' diseases, so that appropriate and timely treatment can be started.

Radiography is only one component of medical testing for clinical diagnosis

- 23 No medical test, including chest radiography, is perfect. Chest radiography can miss some cases of dust-induced lung disease and falsely identify others. In addition, workplace dusts can cause
- medical outcomes that often cannot be diagnosed based on chest radiograph alone. For instance,
- 4 5 6 7 8 9 inhalation of coal mine dust is associated not only with coal workers' pneumoconiosis but also with
- chronic obstructive lung diseases, such as chronic bronchitis and emphysema. In order to be
- accurate and comprehensive in their diagnoses, physicians must synthesize information from
- patients' occupational and medical histories (including dust exposures), symptoms, physical
- examinations, and medical testing. The type of medical testing depends on the suspected 10 disease(s) and may include radiography, lung function testing, laboratory tests, and, in some
- 11 cases, invasive testing such as lung biopsy. The American Thoracic Society (ATS) and other
- 12 medical organizations publish official quidelines for diagnosis and management of respiratory
- 13 diseases such as asbestosis. These guidelines emphasize the importance of using multiple
- 14 diagnostic modalities. When available and appropriate, these guidelines should be used for the
- 15 suspected disease [ATS 2004].

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16 Single radiograph readings are appropriate

- 17 For medical diagnosis purposes, single radiograph readings are appropriate and do not need to be
- 18 done as formal International Labour Office (ILO) classifications or by a certified B Reader.
- 19 However, principles underlying the ILO Classification scheme for the pneumoconioses are
- applicable to clinical radiographic interpretation and can be useful in describing abnormalities, if
- present. Additional readings by a specialist or expert may be helpful in order to confirm a diagnosis
- 20 21 22 23 24 in some situations. Although not needed for clinical diagnosis, ILO classification may eventually be
- required for participation in Federal or State compensation systems (see sections below on
- "Government Program Eligibility" and "Compensation Settings").

25 Timely disclosure of results, appropriate follow-up, and patient education are essential

- 26 27 28 29 30 Once the diagnosis is made, physicians should disclose results to the patient in a timely manner,
- provide appropriate medical follow-up, and educate patients about their illnesses and approaches
- to avoid or minimize further exposure to workplace dusts and other harmful exposures, e.g.,
- tobacco smoke. Further exposure must be reduced to prevent progression of the disease, and
- appropriate treatment can minimize the impact of established disease.

31 Physicians must follow state reporting requirements

- Physicians should be mindful that recognition of occupational lung disease can provide an
- 32 33 34 35 36 37 38 39 opportunity for preventive interventions not only for the affected worker but also for the associated
- workplace, process, agent, or industry. Physicians and other health care providers are
- encouraged, and in some states required, to notify their State of diagnosed or suspected cases of
- occupational pneumoconioses, including silicosis and asbestosis. A chest radiograph classified or
- otherwise interpreted as consistent with the reportable disease is often considered sufficient
- evidence to require reporting. If physicians are not already aware of their State reporting
- requirements, they should contact their state to be apprised of any reporting requirements for which
- they may be responsible. Contacts for State Public Health Departments can be found on the
- 41 Association for State and Territorial Health Officials (ASTHO) Web site (external link).
- 42 43 Physicians should also inform their patients about filing deadlines for state Workers' Compensation
- and Federal Black Lung benefits in order to preserve eligibility. The patient should be advised that
- there are often time limits that apply to how long individuals have to make a claim after they are
- 45 diagnosed with a compensable disease.

References

- 47 Black Lung Clinics Program. Bureau of Primary Health Care, Health Resources and Services
- 48 Administration
- External Link: http://bphc.hrsa.gov/blacklung/default.htm

NIOSH Topic Page: Chest Radiography

Recommendations for Applying the ILO International Classification of Radiographs of Pneumoconioses

- 12 Association of Occupational and Environmental Clinics
- External Link: http://www.aoec.org/
- 3 4 American Thoracic Society. Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos. *Am J Respir Crit Care Med* 2004;170:691-715.
- Association for State and Territorial Health Officials
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Recommended Application of the ILO Classification System in Research and Population Surveillance

Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.

Classifications undertaken for research and population surveillance of the pneumoconioses need to be accurate (valid) and precise (reliable). For example, reliably establishing temporal or geographic trends in disease prevalence or incidence, disease relationships with occupation and industry, and exposure-response relationships are all objectives that require consistent, reproducible scoring of films in order for the underlying effects to emerge. Thus, in these settings, accurately and precisely scoring films in relation to the International Labour Office (ILO) standard films is a critical goal and great care must be taken to attain it.

15 Summary of Recommendations

ILO Classification:	Yes	
B Reader certification:	Yes	
Multiple readings:	Yes	
Blind reading:	Yes	
Quality control films:	Desirable	

16 Further information

17 The role of radiography in epidemiology and related research

The ILO International Classification of Radiographs of Pneumoconioses was designed as a mechanism for assessing occupational lung disease. It is based on classifying the degree of parenchymal lung abnormality on an unknown film on a 12-point scale ranging from 0/- to 3/+ by comparing it to ILO standard films [ILO 2000]. Pleural abnormalities are also identified and classified. Since its inception, ILO Classification has become a critical and necessary tool for investigation of the pneumoconioses. The validity of ILO Classification has been repeatedly demonstrated in many settings and industries. For example, classifications of radiographs of coal miners show clear correlations with dust exposure, lung dust burden, lung pathology, and mortality [Attfield 1992, Ruckley 1984, Miller 1985]. Elsewhere, classifications of radiographs of patients with asbestos-related lung disease were shown to be correlated with lung function [Cotes 1988]. A useful summary of criteria to consider for epidemiologic purposes is given by Mulloy et al. [1993].

Issues of reader variability

It is well known that variation exists not only from reader to reader (inter-reader variation), but also between readings by the same reader (intra-reader variation). Variation has been seen to persist despite careful training and extensive quality control [Fay 1959, Hurley 1982]. To reduce the effect of variation between readers in epidemiologic studies in order to derive the most precise data, it is recommended that at least two, but preferably more, readers each classify all radiographs independently [ILO 2000]. Use of panels reading films simultaneously is not recommended. Rather, readers should classify the radiographs alone and blind to the interpretations of other readers and to any information on the individual. These individual readings can be combined into a single summary classification. Summarization methods that represent the middle of the distribution of readings, such as use of median classifications, are preferable. Summarization methods that do not reflect the central tendency of the range of readings by their nature result in biased determinations and should be avoided.

Select trained and experienced readers

- Readers for epidemiologic studies should be selected to be representative of general reading
- practices: that is, they should not fall at the extremes of the range of variability between readers.
- 4 The readers should be informed about and assessed for inter- and intra-reader variability.
- 5 A pilot trial and use of quality control film interpretation may be useful to assess the extent of inter-
- 6 reader variation. Feedback should be provided to give passive encouragement to those in the
- extremes to moderate their readings. Alternatively, an active procedure of selecting readers based
- on their standing with respect to the others can be adopted.

Quality control

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- 10 As noted above, initial and subsequent interval re-assessment of readers' performance in scoring
- 11 quality control films is useful in documenting systematic differences between readers. Over time,
- 12 variation between repeated classifications of the same films can also be used to assess whether
- 13 "drift" in readers' scoring is occurring. Providing feedback to readers based on quality control
- 14 evaluations is a useful strategy for narrowing the distribution and maintaining reproducibility of
- 15 classifications relative to ILO standard films.
- 16 17 Quality control can be done simultaneously with interpretation of unknown films by placing
- unidentified quality control ("calibration") films with a previously established array of parenchymal
- 18 and/or pleural findings within the set of unknown films being evaluated. An advantage to this
- 19 approach is that it provides the most realistic assessment of how readers classify unknown films.
- 20 21 22 Providing feedback comparing the reader's classification of these films to the previously-
- established classifications has been used to maintain and improve reader performance [Sheers
- 1978]. A National Institutes of Health-sponsored workshop suggested including chest films of
- 23 unexposed workers in epidemiologic studies for purposes of control [Weill 1975].

24 Classify films blind to medical and exposure information

- 25 26 27 28 29 When classifying radiographs for epidemiologic purposes, it is essential to be aware that
- knowledge of supplementary details specific to individuals can introduce bias into results. This
- includes medical or exposure information and other readers' interpretations. [ILO 2000] To avoid
- the effects of any temporal reader drift, films collected over the course of a study can be allocated
- to readers in batches that are random with respect to time and other study characteristics.

30 References

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NIOSH Topic Page: Chest Radiography Recommendations for Applying the ILO International Classification of Radiographs of Pneumoconioses

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Recommended Application of the ILO Classification System in Worker Health Monitoring

Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.

Worker health monitoring is an important tool for preventing disease in occupational settings. For the purposes of this document, it refers to the detection of pneumoconioses in dust-exposed individuals through periodic chest radiography. Positive findings can result in both medical evaluation of the affected worker and workplace interventions that prevent further disease development in both the affected individual and similarly exposed co-workers. Worker health monitoring is considered a secondary prevention measure, intended to provide a backup when primary prevention (e.g., dust exposure monitoring and control) measures fail.

15 Summary of Recommendations

ILO Classification:	Yes
B Reader certification:	Yes
Multiple readings:	Desirable for positive films and a small percentage of negative films
Blind reading:	Not necessary
Quality control films:	Desirable

16 Further information

The role of radiography in monitoring

There is a long history of using chest radiographs in worker health monitoring for the pneumoconioses. Two examples are the <u>Coal Workers' X-ray Surveillance Program (CWXSP)</u>, which is a federal program for the detection of coal workers' pneumoconiosis (CWP) in currently-working underground coal miners, giving affected individuals the right to work in a reduced dust environment. Another program is the <u>Asbestos Medical Surveillance Program (AMSP)</u> (external link), administered by the Navy Environmental Health Center. The Occupational Safety and Health Administration (OSHA) asbestos standard requires that chest radiographs obtained for surveillance of those exposed to asbestos be interpreted and classified by a B Reader, radiologist, or physician with expertise in pneumoconioses. <u>OSHA</u> (external link) also specifies B Readers and the International Labour Office (ILO) Classification in its asbestos safety and health standards for general industry, construction, and shipyard employment.

Physicians and other health care providers are encouraged, and sometimes required, to notify their State of diagnosed or suspected cases of occupational pneumoconioses, including silicosis and asbestosis. A chest radiograph classified or otherwise interpreted as consistent with the reportable disease is often considered sufficient evidence to require reporting. If physicians are not already aware of their State reporting requirements, they should contact their State to learn about any reporting requirements for which they may be responsible. Contacts for State Public Health Departments can be found on the ASSOCIATION Web site (external link).

Balancing costs

When designing a monitoring program, it is important to weigh the cost of failing to detect true disease (false negatives) against the cost of falsely identifying disease (false positives) in health workers. All of the issues discussed in the section on research and surveillance, including interreader variability, reader experience, blinding, and quality control apply in the setting of worker health monitoring. However, in the worker health monitoring setting, approaches to film

NIOSH Topic Page: Chest Radiography

Recommendations for Applying the ILO International Classification of Radiographs of Pneumoconioses

- classification have important social and economic implications. Individuals who have true disease
- 2 3 4 5 but are not identified during health monitoring will not be protected from further exposure, and
- hence will likely suffer disease exacerbation. Ultimately, they may suffer impairment, disability, or
- premature mortality, with the ensuing economic and social costs of treatment, compensation, and
- reduced quality of life. In addition, failing to identify sentinel cases of disease may also result in
- failure to identify risky working situations, letting other workers continue to be at risk of hazards.
- 7 8 9 On the other hand, a health monitoring program that has a high rate of falsely detecting disease
- brings with it the social cost of unnecessary worker concern and the financial cost of medical
- follow-up testing. A health monitoring program may be impractical if the costs of procedures and
- 10 follow-up are excessive compared to program benefits. There must be a balance between sensitive
- 11 and practical surveillance and accurate procedures.
- 12 Two factors impacting sensitivity and specificity are 1) the point (or points) in the scale of
- 13 abnormality that is chosen for decision making (e.g., further follow-up, removal from exposure), and
- 14 2) the use of single or multiple readers, and, in the latter case, how the multiple readings are
- 15 summarized.

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Single versus multiple readings

- 17 In some circumstances, a program organized around single readings of the majority of the
- 18 radiographs may be satisfactory. Such programs may involve a single initial reading for all films,
- 19 followed by a second reading for the subset that shows early abnormality. It is also advisable for a
- second reading to be performed in a small percentage of films initially classified as normal. As a
- 20 21 22 23 24 25 matter of practicality, this percentage may be smaller for larger work forces. In this way, the
- program can be cost-effective, while at the same time safeguarding the objective of disease
- detection. Through use of accurate readers and through careful choice of the abnormality level that
- triggers further evaluation, a program can be sensitive to disease and fulfill its purpose without
- undue cost.
- 26 27 Multiple readings of radiographs can also be used and are employed by at least one ongoing
- monitoring program. All final determinations for the Coal Workers' X-Ray Surveillance Program are
- based upon agreement of two readers, using a specified algorithm [42CFR37 (external link)]. Data
- from this program are also used in population surveillance (see below).
- Requiring readers to regularly interpret quality control films is considered useful in "calibrating"
- 30 31 readers to classify films in a more consistent and precise manner [Fay 1959].
- 32 Whatever approach to radiographic monitoring is undertaken, it is critical that there be a formal
- 33 34 process linking positive findings to organized responses that protect both the affected individual
- and similarly exposed co-workers.

Use of health monitoring data for population surveillance purposes

- Population surveillance refers here to observations and actions involving groups of individuals.
- Information from health monitoring programs can frequently be useful for population surveillance.
- An example of this can be found on the Occupational Respiratory Disease Surveillance (ORDS)
- Web site. For this to be effective, care must be taken to ensure that the health monitoring
- information is representative of the population so that the prevalence statistics are valid and
- unbiased. Particular attention must be given to data management and analysis, and additional
- readings may be necessary to get reliable information. As already noted, identified cases of
- reportable diseases should be reported to State Public Health Departments as required by law. A
- 44 45 listing of State Public Health Departments can be found at the Association for State and Territorial
- Health Officials (ASTHO) Web site (external link).

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NIOSH Topic Page: Chest Radiography Recommendations for Applying the ILO International Classification of Radiographs of Pneumoconioses

1	References
2 3	Coal Workers' X-Ray Surveillance Program. National Institute for Occupational Safety and Health. How can I learn more about my transfer options?
4 5	Asbestos Medical Surveillance Program. Navy Environmental Health Center External Link: http://www-nehc.med.navy.mil/occmed/Asbestos.htm
6 7	Safety and Health Topics: Asbestos. Occupational Safety and Health Administration External Link: http://www.osha.gov/SLTC/asbestos/index.html
8	Association for State and Territorial Health Officials External Link: http://www.astho.org/
10 11	Specifications for Medical Examinations of Underground Coal Miners. 42CFR37 External Link: http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr37_02.html
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Recommended Application of the ILO Classification System in **Determining Government Program Eligibility**

4 5 Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.

8 The information on this page refers to radiograph readings that are made for certain federal programs that award disability benefits.

10 **Summary of Recommendations**

ILO Classification:	Refer to program
B Reader certification:	Refer to program
Multiple readings:	Refer to program
Blind reading:	Refer to program
Quality control films:	Refer to program

11 Further information

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- 12 Physicians should follow federal regulations regarding medical testing for the Black Lung 13 Benefits Program
- Physicians performing medical testing for the Black Lung Benefits Program should follow 14
- 15 regulations found in 20CFR718.102, 718.202, and Appendix A (external link). These regulations
- 16 specify what medical testing must be done as well as the film and equipment that must be used for
- radiography. Chest radiographs must be classified using the International Labour Office (ILO)
- 17 18 Classification system.
- 19 Physicians should follow federal regulations regarding medical diagnosis of chronic 20 silicosis for Energy Employees Occupational Illness Compensation Program
- The Energy Employees Occupational Illness Compensation Program Act of 2000 provides
- compensation for employees or eligible survivors of employees of the Department of Energy, its
- predecessor agencies, and its contractors and subcontractors who became ill as a result of the work performed in the production and testing of nuclear weapons. Silicosis is a covered condition
- under the Act. Physicians should follow regulations regarding medical diagnosis of chronic silicosis
- for the Energy Employees Occupational Illness Compensation Program (external link). A written
- diagnosis of silicosis must be made by a medical doctor along with a chest radiograph, results of
- other imaging techniques, or a lung biopsy. If a chest radiograph is submitted, it must be
- interpreted by a NIOSH certified B Reader.
- 30 Coal workers diagnosed with pneumoconiosis (black lung) should contact the nearest Black 31 Lung Benefits Office to determine their eligibility
- The Federal Black Lung Benefits Program is completely separate from the State Worker's
- Compensation programs. Some miners may qualify for one program and not the other. The Black
- Lung Benefits Act was passed in 1969 [20CFR718, 20CFR725 (external links)]. This Federal
- program provides payments and medical treatment to coal miners who are totally disabled from
- pneumoconiosis (black lung) arising from their employment in or around the nation's coal mines. In
- select cases, payments may be paid to eligible surviving dependents. To find out about eligibility for
- Federal Black Lung Benefits, contact the nearest Black Lung Benefits Office (external link).

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Workers diagnosed with pneumoconiosis should contact the State Office of Workers' 2 Compensation to determine their eligibility 3 Federal benefits programs are completely separate from State Workers' Compensation programs. 4 Some individuals may qualify for one program and not the other. State disability benefits and 5 6 7 compensation differ by state, so contact the State Office of Worker's Compensation (external link) to learn about compensation from the State Government. There are often time limits that apply to how long individuals have to make a claim after the worker is diagnosed with a compensable disease, so workers should be encouraged to avoid delay in contacting the State Office. 9 Workers diagnosed with silicosis due to mining of tunnels at Department of Energy 10 Facilities in Nevada or Alaska should contact the Energy Employees Occupational Illness 11 Compensation Program to determine their eligibility The Energy Employees Occupational Illness Compensation Program Act of 2000 provides 13 compensation for employees or eligible survivors of employees of the Department of Energy, its 14 predecessor agencies, and its contractors and subcontractors who became ill as a result of the 15 work performed in the production and testing of nuclear weapons. Silicosis is a covered condition 16 under the Act. Eligible employees are those who were exposed to silica for a total of at least 250 17 work days during the mining of tunnels at a Department of Energy facility located in Nevada or 18 Alaska for tests or experiments related to an atomic weapon. Individuals with these exposures and 19 seeking compensation should contact the Energy Employees Occupational Illness Compensation 20 Program [EEOICPA Web site (external link)]. 21 Employers should follow the OSHA asbestos standard 22 23 24 25 26 27 The Occupational Safety and Health Administration (OSHA) asbestos standard (external link) requires that chest radiographs obtained for surveillance of those exposed to asbestos be interpreted and classified by a B Reader, radiologist, or experienced physician with expertise in pneumoconioses. OSHA also specifies B Readers and the International Labour Office (ILO) Classification in its asbestos safety and health standards for general industry, construction, and shipyard employment. 28 References 29 Standards for Determining Coal Miners' Total Disability or Death Due to Pneumoconiosis. 30 31 External Link: http://www.dol.gov/dol/allcfr/Title_20/Part_718/toc.htm Claims for Benefits Under Part C of Title IV of the Federal Mine Safety and Health Act, As Amended. 20CFR725 External Link: http://www.dol.gov/dol/allcfr/Title 20/Part 725/toc.htm Black Lung Benefits Offices. Division of Coal Mine Workers' Compensation Program and District Offices, Department of Labor External Link: http://www.dol.gov/esa/contacts/owcp/blcontac.htm Energy Employees Occupational Illness Compensation Program Act of 2000, as described on the US Department of Labor compliance assistance web site. External Link: http://www.dol.gov/esa/regs/compliance/owcp/ca_eeoic.htm 41 42 State Workers' Compensation Officials. US Department of Labor External Link: http://www.dol.gov/esa/regs/compliance/owcp/wc.htm 43 44 Safety and Health Topics: Asbestos. Occupational Safety and Health Administration External Link: http://www.osha.gov/SLTC/asbestos/index.html

Recommended Application of the ILO Classification System in **Compensation Settings**

3 4 5 Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final 6 text will modified based on input received from stakeholders.

- The International Labour Office (ILO) recognizes the limitations of the use of the ILO Classification System in the decision making process for awarding compensation. The 2000 ILO Classification Guidelines state explicitly that classification "does not imply legal definitions of pneumoconiosis for
- 10 compensation purposes and does not set or imply a level at which compensation is payable" [ILO 2000]. As discussed in the Medical Diagnosis section, the diagnosis of pneumoconiosis is best
- made by considering both the chest radiograph and other data, including the medical and
- 13 occupational history, physical examination, other types of chest imaging and laboratory tests, and
- 14 sometimes biopsy.
- 15 Despite these cautions, ILO classifications that fit certain definitions of abnormality are frequently considered in decisions concerning compensation awards. To achieve consistency and fairness in 17 these proceedings, it is important that such classifications be standardized and reproducible across 18 geography and time. Societal considerations, such as affordability of evaluations and 19 consequences of misclassification, are important considerations in compensation proceedings. 20 21 22 Balancing these considerations is an issue of both science and societal values. Differing venues may legitimately choose different approaches, so these recommendations are offered as guidance

23 **Summary of Recommendations**

rather than absolutes.

ILO Classification:	Desirable			
B Reader certification:	Desirable			
Multiple readings:	Desirable (with caveats)			
Blind reading:	Desirable			
Quality control films:	Desirable			
115Cu				
Further information				

24 **Further information**

25 Follow guidelines for expert witnesses

- The American Medical Association and the American College of Radiologists and other medical organizations have published guidelines for physicians serving as expert witnesses. All of them
- discuss the need to be impartial, objective, and unbiased. Testimony must be scientifically valid
- and be able to withstand peer review [ACR 2002, AMA].

30 Chest radiograph readings and compensation

The ILO system provides for classification of parenchymal and pleural abnormalities. Parenchymal lung abnormality is classified on a 12-point scale ranging from 0/- to 3/+. Pleural abnormalities are divided into pleural plaques (localized pleural thickening), costophrenic angle obliteration and diffuse pleural thickening. Parenchymal abnormalities classified as 1/0 or greater are frequently considered to be consistent with the presence of pneumoconiosis. In general, this threshold of 1/0 is also used in compensation proceedings to document the presence of pneumoconiosis. As stated above, the ILO itself states that classification does not imply definitions of pneumoconiosis for compensation purposes [ILO 2000].

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Single versus multiple readings

Despite concerns raised by the ILO, use of ILO Classification as performed by B Readers can be a useful tool in compensation proceedings. As the ILO states, "the object of classification is to codify the radiographic abnormalities of the pneumoconioses in a simple, reproducible manner" [ILO 2000]. Reproducibility is critical to using chest radiographic interpretations in compensation settings. Lack of accuracy and imprecise interpretation could lead to unequal treatment of claimants. To limit the impact of reader variability in scoring chest radiographs relative to ILO standard films, ILO recommends "that, in epidemiological studies, at least two, but preferably more, readers each classify all radiographs independently" [ILO 2000]. It may seem reasonable to consider applying the same standard in compensation proceedings after considering issues related to the effectiveness of the use of multiple readings (addressed below) and possible associated costs.

There are important caveats that should be considered in applying a multiple reading approach to compensation proceedings. As already discussed, there is inter- and intra-reader variability. Groups composed of individual readers with extreme tendencies of under- or over-reading of abnormalities can be expected to produce similarly extreme interpretations. Thus, use of multiple readings in itself will not guarantee accurate readings. There are several ways to deal with this issue and improve accuracy. One would be to select readers who are in the mainstream of reading tendencies and exclude those with extreme tendencies. This can be achieved in epidemiological studies by analyzing how groups of readers interpret the same films. In compensation proceedings, exclusion of readers may raise many issues and difficulties. Although desirable, selection based on quality control evaluation involving classification of test films does not necessarily guarantee how readers will classify actual unknown films. Similarly, interval quality control evaluation separate from actual readings, which is also desirable, does not guarantee that actual readings will be free of reader bias.

One potential solution to these issues might be to perform continuous quality control by mixing quality control ("calibration") films with those being read for compensation applications, with the identity of both sets of films hidden to prevent recognition of their source. Providing feedback comparing the readers' film classifications to previously-established classifications can be used as a tool to improve reader performance [Sheers 1978]. Furthermore, if sufficient numbers of quality control films are classified to achieve appropriate statistical power, evaluation of how readers classify these films can provide objective evidence of readers' performance and possible bias. However, the effectiveness of this approach in compensation proceedings has not been documented.

Another caveat to consider is how the classifications of multiple readers are combined into a single summary classification. Obtaining multiple readings and deriving summary classifications is a common strategy for improving precision. However, the approach to summarization can have an important effect on results. For instance, even if readers are providing accurate readings, methods that require consensus may reduce the proportion of radiographs read as positive to that, or below that, of the most stringent reader, thus compromising accuracy. On the other hand, use of median determinations will tend to reflect the center of the distribution of readers. Assuming the distribution is balanced, this may improve precision without negatively affecting accuracy. Although increasing the number of readers would theoretically increase the precision of readings, cost and complexity also increase with the number of readers. Depending on local circumstances, views may vary as to the specific number of readers that is optimal.

Classify films blind to medical, exposure, and contextual information

When classifying radiographs it is desirable that the reader does not consider any other information about the individuals being studied, including medical data, exposure information, the context and consequences of the reading, or other readers' interpretations. Awareness of supplementary details specific to individuals can introduce bias into results. This information should not be available to the reader at the time of chest radiograph classification but can be considered later when the chest radiograph classification is integrated with other clinical information to formulate a diagnostic assessment. Reading in a blinded fashion also has the potential to limit the appearance that conflict of interest is affecting results.

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2 **Best Technical Practices** 3 4 5 Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final 6 text will modified based on input received from stakeholders. 7 8 9 Radiograph classifications constitute a valid methodology for detecting and assessing certain occupationally-induced lung diseases. To this end, the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses was designed as a systematic 10 mechanism for assessing occupational lung disease. The usefulness of the approach has been 11 demonstrated repeatedly. Classifications of radiographs show clear correlations with dust 12 exposure, lung dust burden, lung pathology, and mortality [Attfield 1992, Ruckley 1984, Miller 13 1985]. Elsewhere, for example, classifications of patients with asbestos related lung disease were 14 correlated with lung function [Cotes 1988]. 15 In order for the method to be applied optimally, the best reading practices shown in these pages 16 should be adopted. Moreover, the following technical aspects should be given consideration. 17 Good-quality radiographic techniques and equipment are essential 18 19 It has long been recognized that both the technique and the equipment used for chest radiographic imaging of dust-exposed workers affect the radiographic appearance of lesions, and that this can 20 21 22 influence the classification of a radiograph for disease. Consequently, readers may find it difficult to use the International Labour Office (ILO) Classification system if the quality of chest radiographs is suboptimal [ILO 2000]. When taking radiographs for assessment using the ILO Classification, a protocol giving clear quality control guidelines should be adopted and employed. For example, in the Coal Workers' X-Ray Surveillance Program, administered by the National Institute for Occupational Safety and Health (NIOSH), there are strict requirements on the radiograph film, exposures, and equipment that must be used. Additionally, before films may be submitted under the program, sample images from each radiograph unit must be evaluated and approved by NIOSH [42CFR37 (external link)]. 29 The role of the NIOSH B Reader Program 30 31 32 33 In the United States, the B Reader Program has played a major role in advancing knowledge of radiographic classification using the ILO system. The B Reader certification examination, administered by NIOSH, is a rigorous evaluation of physicians' capability to identify and appropriately categorize radiographic changes of dust-related lung disease. Physicians who classify chest radiographs for certain federal surveillance programs may be 35 36 37 38 39 required to be an A or B Reader. For example, the Coal Workers' X-Ray Surveillance Program (CWXSP), as mandated by the Federal Mine Safety and Health Act of 1977, requires that physicians who classify radiographs for the program be A or B Readers for the first reading and B readers for subsequent readings [42CFR37 (external link)]. The Asbestos Medical Surveillance Program (AMSP) (external link), administered by the Navy Environmental Health Center, requires 40 that radiographs be read by a local radiologist for the first reading and then classified by a B 41 Reader for the second reading. 42 43 The Occupational Safety and Health Administration (OSHA) asbestos standard (external link) requires that chest radiographs obtained for surveillance of those exposed to asbestos be 44 interpreted and classified by a B Reader, radiologist, or experienced physician with expertise in 45 pneumoconioses. OSHA also specifies B Readers and the ILO Classification in its safety and 46 health standards for general industry, construction, and shipyard employment.

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